

REMARKS

Claims 1-73 are pending. Claims 1-72 were restricted by the Examiner pursuant to the restriction requirement of April 6, 2006. Applicants traverse the restriction requirement, for the reasons noted herein.

Claims 1-6, 13, 18, 19, and 21-24 are amended herein, while claim 73 is newly added. No new matter is introduced by the amendments or new claim, which are fully supported by the application as filed.

ELECTION

Applicants elect restriction group I (claims 1-5), with traverse. New claim 73 is similar to previous claim 21, which was subject to an election of species requirement in the Restriction Action. Although not formally required at present, to facilitate prosecution, Applicants additionally elect the species "arthritis" to facilitate prosecution of elected group I. All elected claims are readable on the elected species.

TRAVERSAL OF THE REQUIREMENT

Applicants traverse the restriction requirement, as detailed below.

First, Applicants note that independent method claims 1, 6, 13, 18, 19, 22 and 24, of groups I-IV are closely related, all involving administration of the IL27R/WSX-1 ligand. The claims differ only in the selection of the target patient for administration. Accordingly, these claims and dependent claims thereon could all be grouped into a single restriction group without creating any undue search or examination burden. Similarly, independent claims 33, 38, 43, 48, 53, 58, 63 and 68 are closely related, differing only in the selection of the target patient for administration of an agent that increases WSX-1 activity. Thus, these claims, with their dependents can also be searched and examined together without undue burden. Applicants respectfully submit that the most logical grouping of claims for restriction in the present case would be:

- I. claims 1-26 and new claim 73;
- II. claims 27-32;
- III. claims 33-72.

In the event that the Examiner adopts this grouping of the claims, Applicants elect resulting group I.

With respect to the “further restriction” of group IV based upon the Markush members of claim 20, Applicants note that this additional restriction is improper as a matter of law. While this issue may be moot in the present case, due to the restriction election noted above, Applicants note that current proposed changes to divisional practices in the Patent Office have profound cost and procedural implications, and, accordingly, Applicants address these issues of further restriction here, reserving the right to further traverse any and all restriction issues in any and all continuation or divisional applications.

Applicants note that the proper procedures to be followed with respect to the unenumerated “groups” of claim 20 are found at 37 C.F.R. § 1.46 and MPEP 803.02, and relate to “election of species” rather than “restriction” *per se*. While the Office is certainly free to require election of species to simplify initial examination, the Office simply has no statutory authority to *reject* a claim for “misjoinder of invention” (the *per se* definition of restriction as applied to a single claim; *See In Re Webber* 198 USPQ 328 (CCPA 1978) and *In Re Haas* 198 USPQ 334 (CCPA 1978)).

This lack of statutory authority is further clarified with respect to Markush-style claims in the seminal case of *In re Harnish* 206 USPQ 300 (CCPA 1980). *Harnish* holds that Markush claims lacking unity may be *rejected* on that basis—but *Harnish* also expressly holds that lack of unity provides no basis at all for *restriction*, i.e., that issues of unity are gleaned from judicial precedent and *not* from 35 USC § 121. In *Harnish*, the Court indicated that the requirements for making a *rejection* for lack of unity include that the elements so rejected must be “repugnant to scientific co-classification.” This standard (which is unrelated to restriction practice in any event) presents a high hurdle, and can *never* be met by elements which are captured within a single genus of an independent claim as in the present case (“immune hyperactivity disorders”). This is because the terms, *by definition*, are appropriately co-classified within the genus of the generic independent claim.

Because the MPEP seems at first glance to consider restriction practice of Markush style claims with respect to Unity of Invention (MPEP 803.02), a great deal of confusion has, unfortunately, become commonplace in the Office as to appropriate restriction

practice, when considering questions of restriction practice for Markush style claims. It is instructive to consider how this section arose in the MPEP to understand what the law is and what it is not when performing this analysis.

After the *Weber* decision, noted above, a previous version of 803.02 that purported to fashion a rejection for “misjoinder” of a Markush-style claim was literally cancelled out of the MPEP. That is, for a time, MPEP 803.02 simply stated:

the subject matter formerly under this subtitle has been cancelled in view of the decisions *In Re Weber et al.* 198 USPQ 328 (CCPA 1978) and *In Re Haas* 198 USPQ 334 (CCPA 1978).

It was plainly well understood that *Weber* and *Haas* categorically and unequivocally forbade the Office from making such “restriction rejections.” In 1980, the Courts again considered the issue of misjoinder of invention in the case of *In Re Harnisch* 206USPQ2d 1059, a case which considered whether there was a *non-statutory* basis for a rejection for “lack of unity” *that was entirely distinct from restriction practice authorized by 35 USC § 121*. The *Harnisch* Court was plainly concerned that the two issues would be confused, noting that:

It should be clear from what we have said that we adhere to our holdings in *In re Weber*, *supra* and *In Re Haas* (*Haas II*), *supra*. Nothing we have said herein is intended to change or modify them in any way; nor do we think anything said could be construed to have such an effect. The “unity of invention” concept is not to be confused with the “misjoinder” under 35 USC 121 rejection employed in *In re Weber*. In *Weber*, we dealt with the use of 35 USC 121, which deals only with restriction requirements, to support the rejection of a single claim. Here we are concerned only with the rejection of a single claim on the distinct ground that it is directed to an improper Markush group.

The Court’s concern that the Patent Office would confuse the issues of divisional practice under 35 USC § 121 and non-statutory unity of invention considerations that are entirely separate from restriction practice has, unfortunately, proven to be well founded. In reinstating MPEP § 803.02, the organizers of the MPEP addressed *Harnisch* (it is the Court decision that now fundamentally underlies the relevant section), but awkwardly left the original previously cancelled headings for the section in place, seeming to suggest that the “unity of invention” issue under *Harnisch* is one of restriction practice. As the Court plainly, expressly and repeatedly made clear (*see, e.g., above*), it simply is not.

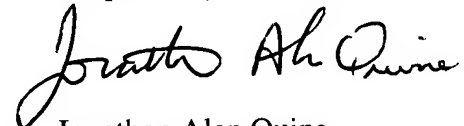
Indeed, while the *Harnish* Court recognized the *possibility* of improper co-classification, the Markush members in that case (a group of dyes) were held to be properly co-classified. Underscoring the rarity of findings of improper co-classification, and the high hurdle presented by the *Harnish* Court, Applicants are aware of no case citable as precedent since the *Harnish* decision that has actually found improper co-classification of Markush elements.

In short, the proper approach when addressing Markush members is to use standard election of species practices. Applicants have already noted a representative species for examination, above (arthritis).

In the event that the Restriction Requirement is maintained with respect to the division of claim 20 into multiple groups, Applicants request an Examiner Interview, prior to issuance of any substantive action.

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Respectfully submitted,



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ATTACHMENTS

- (1). Petition to extend time through the date of this amendment and response to restriction;
- (2). Information Disclosure Statement;
- (3). PTO-1449 Form;
- (4). Change in Entity Status to Large Entity;
- (5). Transmittal;
- (6). Fee Transmittal;
- (7). Receipt Acknowledgement Postcard.